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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,272	02/06/2002	H. Andrew Strong	273012012500	1974

25225 7590 03/10/2011

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ART UNIT	**PAPER NUMBER**
1627	

NOTIFICATION DATE	DELIVERY MODE
03/10/2011	ELECTRONIC

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte H. ANDREW STRONG, MOHAMMAD AZAB,
YONG HAO, JOHN MILLER KOESTER, and
TROY ALBERT REAVES, JR.

Appeal 2010-002076
Application 10/072,272
Technology Center 1600

Before DONALD E. ADAMS, FRANCISCO C. PRATS, and
STEPHEN WALSH, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This appeal under 35 U.S.C. § 134 involves claims to a method for treating an occult choroidal neovascular lesion. The Examiner rejected the claims as obvious.

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

"Eighty to ninety percent of the severe vision loss due to AMD [age-related macular degeneration] . . . is attributable to the form characterized by choroidal neovascularization (CNV), also called 'wet' AMD. CNV is an ingrowth of choroidal capillaries through a break in the outer aspects of Bruch's membrane" (Spec. 1).

"CNV in wet AMD can be generally divided into two classes, 'classic' CNV[] and 'occult' CNV. The two forms are distinguishable by angiography conducted with fluorescein dye" (*id.*).

Appellants' invention "is directed to a method to treat occult CNV lesions using photodynamic therapy [PDT]" (*id.* at 4), which is "a two-step process consisting of an intravenous injection of a photosensitizer (light-activated drug) [such as verteporfin] followed by light application" that selectively destroys the CNV lesion without significant damage to overlying retinal tissue (*id.* at 3).

The Specification expresses surprise that PDT successfully treated occult CNV, "in view of a study (Arch Ophthalmol. 117:1329-1345 by the TAP Study Group), which showed that lesions classified as predominantly classic had a large treatment benefit with verteporfin PDT, whereas lesions classified as minimally classic did not" (*id.* at 4).

Claims 1, 2, and 5-20 stand rejected and are on appeal (App. Br. 2).[2] Claim 1, the only independent claim, is representative and reads as follows:

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[2] Appeal Brief filed February 17, 2009.

> 1. A method for treating an occult choroidal neovascular (CNV) lesion in a subject comprising
>
> selecting a subject with an occult CNV lesion comprising an occult component of >50% and <100% of the lesion and assessed as having either (a) a small lesion with a size less than 5 disc areas, or (b) poor visual acuity of less than 65 letters prior to treatment, or both (a) and (b); and
>
> providing photodynamic therapy (PDT) to the subject having said CNV lesion.

The following rejections are before us for review:

(1) Claims 1, 2, 5-12, 14-18, and 20, under 35 U.S.C. § 103(a) as obvious over TAP Report 1[3] (Ans. 3-6); and

(2) Claims 13 and 19, under 35 U.S.C. § 103(a) as obvious over the TAP Report and Zeimer[4] (Ans. 6-7).

DISCUSSION

The Examiner cites the TAP Report as disclosing a study on the efficacy of photodynamic therapy using verteporfin, which, according to the Examiner, benefitted "patients with ≥50% classic CNV (or ≤50% occult CNV). Furthermore, the upper limit of the claimed invention (99% occult CNV) is also obvious because of the teaching that 'the subgroup with no classic CNV (100% occult CNV) had a large treatment benefit' from pg. 1339 of the TAP Report" (Ans. 4).

Thus, the Examiner contends:

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[3] Neil M. Bressler (corresponding author) et al., *Photodynamic Therapy of Subfoveal Choroidal Neovascularization in Age-related Macular Degeneration with Verteporfin. One-Year Results of 2 Randomized Clinical Trials--TAP Report 1*, 117 ARCH. OPHTHALMOL. 1329-1345 (1999).
[4] U.S. Patent No. 5,935,942 (filed December 14, 1994).

> [I]t would have been obvious to one of ordinary skill in the art at the time of invention to practice the method steps of TAP Report to treat patients with occult CNV lesion having an occult component of >50% to <100% of the lesion, because as shown by the Report, one of ordinary skill in the art would have had a reasonable expectation of success to observe some degree of improvement in ocular condition of the patients suffering from said occult CNV.

(*Id.* at 6.)

Appellants contend that the TAP Report shows that PDT using verteporfin was no more effective than placebo in improving visual acuity in the subgroup of patients having lesions in which >50% and <100% of the lesion area had an occult component (App. Br. 6-9). Thus, Appellants conclude:

> No rationale has been provided to suggest why one of skill in the art would choose to disregard a major finding of a multi-center clinical research study and attempt to treat patients having occult CNV lesions with an occult component of >50% to <100%, for whom the TAP Report 1 clearly states that PDT treatment is ineffective in improving visual acuity or slowing progression of occult CNV.

(*Id.* at 9.)

Moreover, Appellants contend, while the TAP Report characterized the studied eyes with respect to Appellants' claimed parameters of lesion size and visual acuity:

> [T]he TAP Report 1 provides no correlation between the percent occult character of the patient's CNV lesion and visual acuity or lesion size, and no guidance is provided that would lead to the selection of the claimed sub-population having poor visual acuity, or small lesion size, or both, in combination with

> occult CNV lesions having an occult component >50% and <100% lesion area.

(*Id.* at 10.) Thus, Appellants conclude, "the TAP Report 1 provides neither a reasonable expectation of success nor any motivation to practice the instantly claimed methods" (*id.*). Appellants also contend that their Specification presents evidence of unexpected results (*id.* at 13-14).

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

Regarding the type of rejection before us, in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the Supreme Court emphasized "an expansive and flexible approach" to the obviousness question, but also reaffirmed the importance of determining "whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue." *Id.* at 418 (emphasis added).

Ultimately, therefore, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

We agree with Appellants that the Examiner's obviousness conclusion is not supported by a preponderance of the evidence. Claim 1 requires the practitioner to provide photodynamic therapy (PDT) to a specific population

of patients, those having a CNV lesion in which the occult component of the lesion constitutes greater than 50% but less than 100% of the lesion. The treated patients must also (a) have lesions smaller than 5 disc areas, or (b) have a visual acuity less than 65 letters, or meet both criteria (a) and (b).

As Appellants point out, the TAP Report evaluated the efficacy of PDT treatment on patients in which the occult component constituted greater than 50% but less than 100% of the CNV lesions, as recited in claim 1 (*see* TAP Report 1340 (Table 5)). As seen in the TAP Report, the percentage of patients that lost less than 15 letters of visual acuity 12 months after PDT treatment was essentially the same (0.6% percentage point difference) as in the placebo recipients (*see id.*).

Based on these results, the TAP Report explicitly states that "[n]o appreciable difference was observed in the group of patients with lesions in which the area of classic [i.e. non-occult component of the] CNV was greater than 0% but less than 50% of the area of the entire lesion at baseline" (*id.* at 1339; *see also* 1341 ("lesions in which the area of classic CNV was greater that 0% but less than 50% of the area of the entire lesion as baseline had no visual acuity benefit with treatment")). The TAP Report ultimately recommended "verteporfin therapy in the treatment of patients with predominantly classis sub-foveal CNV caused by AMD, especially when the lesion has classic CNV *and no occult* CNV" (*id.* at 1344 (emphasis added)).

Thus, based on the Report's recommendation, and the fact that the TAP Report found essentially no difference between PDT and placebo treatments with respect to the patients meeting the occult percentages recited in Appellants' claim 1, we are not persuaded that an ordinary artisan would have been prompted to treat those patients with PDT, as claim 1 requires.

We acknowledge, as the Examiner points out, that PDT produced a 46% difference compared to placebo in patients with lesions with *some* occult component to their lesions (*see* TAP Report 1340 (Table 5)). Again, however, when the TAP Report analyzed the results of the subpopulation having lesions meeting the occult percentages of claim 1, no benefit beyond that observed in placebo patients was seen.

We also acknowledge the TAP Report's statement that the "subgroup with no classic CNV had a large treatment benefit; however, the number of patients in this subgroup was small and did not meet the eligibility criteria for the trials" (TAP Report 1339). Given the Report's finding that the results from this subset of patients was not usable because the subgroup was too small, we are not persuaded that an ordinary artisan would have been prompted to go beyond the study's ultimate recommendation of treating patients with predominantly classical, as opposed to occult, lesions, as claim 1 requires.

To further tip the preponderance of the evidence toward non-obviousness, Appellants have presented data supporting their position that, in contrast to the TAP Report's suggestion that predominantly occult lesions are not amenable to PDT treatment, selecting the claimed subpopulation of such patients, with predominantly occult lesions and either or both of small lesions (less than 5 disc areas) and poor visual acuity (less than 65 letters), produces a significant visual acuity benefit 24 months after treatment as compared to placebo (*see* Spec. 45 (Table 2)).

"[W]hen an applicant demonstrates *substantially* improved results . . . and *states* that the results were *unexpected*, this should suffice to establish

unexpected results *in the absence of* evidence to the contrary." *In re Soni*, 54 F.3d 746, 751 (Fed. Cir. 1995).

In the instant case, while the Examiner states that the results are not commensurate in scope with the claimed subject matter, and do not present "a clear and convincing case of unexpected results" (Ans. 9), the Examiner has not provided any clear explanation or evidence as to why that is the case. Given the results presented by Appellants compared to the results obtained by the TAP Report, and the absence of any clear explanation or evidence from the Examiner as to why Appellants' data is insufficient, we are not persuaded that the Examiner had a proper basis to discount Appellants' proffered evidence.

In sum, for the reasons discussed, we are not persuaded that a preponderance of the evidence supports the Examiner's prima facie case of obvious, and even if this were considered a close case in that regard, the Examiner has not adequately explained why Appellants' evidence of unexpected results is insufficient to overcome a prima facie case of obviousness based on the TAP Report. We therefore reverse the Examiner's rejection of claim 1, and its dependents, as obvious over the TAP Report.

Claims 13 and 19 depend ultimately from claim 1. As the Examiner did not identify any teachings in Zeimer that remedy the shortcomings discussed above with respect to the TAP Report vis-à-vis claim 1, we also reverse the Examiner's rejection of claims 13 and 19 over the Tap Report and Zeimer.

SUMMARY

We reverse the Examiner's obviousness rejection of claims 1, 2, 5-12, 14-18, and 20 over the TAP Report 1.

We also reverse the Examiner's obviousness rejection of claims 13 and 19 over the TAP Report and Zeimer.

REVERSED

cdc

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